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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,440	10/03/2006	Hans-Peter Wild	251646	1885

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EXAMINER	
CHAWLA, JYOTI	

ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
10/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,440	WILD ET AL.	
	Examiner	Art Unit	
	JYOTI CHAWLA	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/11/06, 5/11/09, 11/9/09, 12/14/09.

DETAILED ACTION

Preliminary amendment to the claims of 4/11/2006 has been considered and claims 1-7, 9-10 and 12 are pending and examined in the current application.

Claim Objections

Claims 1-7, 9-10 and 12 are objected to because of the following informalities:

Claims 1-6 and 10 include the term "characterized in that" which is not a standard US accepted phrase. Applicant is suggested to change the phraseology to a more accepted US term, such as "wherein" to clarify the meaning of the claim. Appropriate correction is required.

Claims 1-6 are objected for the recitation of "fresh milk" as it is not clear as to the difference between fresh milk and milk as recited in claims 1, 2 and 5. For the purpose of examination, the term "fresh milk" will be regarded to be "milk".

Independent Claims 1 and 7 are objected for the recitation of the term "and/or" in the claims, which will be regarded to be equivalent of either "and" OR "or"; i.e. the "/" is equivalent of or.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1) **Claims 1-2, 5, 7** are rejected under 35 U.S.C. 102(b) as being anticipated by

Cravero (US 6033691), hereinafter Cravero.

Regarding **claims 1-2 and 5,** Cravero teaches a protein powder (Column 6, line 60, Column 9, line 43), including at least one protein source (non fat milk as taught by Cravero in Column 3, lines 12-14) and carboxylmethylcellulose (Column 3, lines 20-21), i.e., one stabilizer, selected from esterified pectin and/or carboxylmethylcellulose, wherein the protein source can be cow's milk or skim milk (Column 5, lines 50-55), which fulfills the limitations of claims 2 and 5 of protein source consisting of milk or fresh milk selected from the group consisting of cow milk, sheep milk, goat milk, mare milk, whey, soy milk, oat milk and rice milk (**Claim 2**) and group consisting of cow milk, soy milk, whey and mixtures thereof (**claim 5**).

It is noted that whereas claim 1 is a product claim, the newly added limitation of "obtained by: mixing a protein source with a stabilizer, heating the mixtures homogenizing the mixture, and drying the mixture to obtain a powder" as recited in lines 3-4 of claim 1", is a process limitation.
Similarly the limitation of "the mixing of the protein source with a stabilizer takes place in a liquid medium" as recited in claim 2 is a process limitation.
As such claims 1-2 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding **claim 7**, Cravero teaches a method of producing a protein powder (Column 9, line 43), including at least one protein source (milk, Column 3, line13) and as stabilizer Cravero teaches carboxymethylcellulose (Column 3, lines 20-22), which fulfills the claimed limitation of one stabilizer selected from esterified pectin and/or

carboxymethylcellulose. The method as taught by Cravero comprising the claimed steps: mixing the protein source with a stabilizer (Column 3, lines 12-22). Cravero discloses of heating the mixture in Column 3, line 15, where pasteurization is taught and Column 3, lines 18-25, where temperature of the mixture is about 40°C and also heating the mixture for no higher than 60°C to concentrate the product in Column 6, lines 50-55. Regarding homogenizing the mixture see Cravero (Column 3, lines 115-16 and 24-25). Regarding the limitation drying the mixture to obtain a powder Cravero teaches heated drying method and lyophilization or freeze drying (Column5, lines 35 and Column 6, lines 52-60). Thus the method as recited in claim 7 is taught by Cravero.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A) **Claims 3-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cravero (US 6033691).
Cravero has been applied under 35 USC 102 (b) for the rejection of claims 1-2.
Note: Milk composition obtained from http://chestofbooks.com/food/recipes/Boston-Cooking-School/Milk-Composition.html has been relied upon as evidentiary reference for the milk protein content.

Cravero as applied to claim 1, teaches a product having pH in the range of 4.45-4.65 (Column 7, lines10-15), which includes pH values that overlap applicant's claimed value of pH of less than 4.5. Regarding the overlapping of ranges between the invention and prior art composition it is noted that in the case where the claimed ranges "overlap or lie inside the ranges disclosed by the prior art" a prima facie case of obviousness exists (In re Wetheim, 541 F2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).
Further regarding the limitation that the pH of less than 4.5 is to be achieved before drying, it is noted that drying is a process limitation, which makes claim 3 a product by process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Cravero as applied to claim 1, teaches of protein powder wherein the product comprises from 50-99.8% biologically active milk (Column 7, table in lines 25-40) before drying. Milk typically comprises from 3.5% protein, 4% fat, 0.75% mineral or ash, 4.75% lactose and 87.25% water by weight, as evidenced by milk composition reference. Based on the milk composition, solids content of milk is about 12.75% by weight and the protein content is 27.5% of the total milk solids content.
Based on the solids content of milk, and rest being sugars and vitamins and minerals, all solids, the protein powder obtained from compositions disclosed by Cravero will contain 3.1% to about 27% of protein (In examples I, II and III the milk component is 50% of the composition, milk solids =6.4 out of total solids of 56.3 (adding all the other ingredients for each of the compositions I, II and III separately) which makes the protein content of 3.1%. For examples IV and V of Cravero's Column 7, milk component is 99.8%, i.e., milk solids are 12.75 out of a total of 12.77 and the protein content is 27.5% of milk solids so the protein component is 27%).
Thus, the protein component of the composition as disclosed by Cravero of 3.1 to 27% by weight overlaps applicant's claimed range of 10-90% protein content by weight as recited in **claim 4**. Regarding the overlapping of ranges between the invention and prior art composition it is noted that in the case where the claimed ranges "overlap or lie inside the ranges disclosed by the prior art" a prima facie case of obviousness exists (In re Wetheim, 541 F2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

B) **Claims 6, 9 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cravero (US 6033691) in view of Wudel et al (US 4497841), hereinafter Wudel.

Cravero has been applied under 35 USC 102 (b) for the rejection of claims 1-2, 5 and 7 and under 35 U.S.C. 103(a) for the rejection of claims 3-4.

Cravero as applied to claim 1, teaches of protein powder wherein the product comprises carboxymethylcellulose as stabilizer (Column 3, lines 20-21 and claim 1), however, the

reference is silent about the amount of stabilizer as recited in **claim 6.** However, addition of stabilizer in the recited range of the applicant was known in the art at the time of the invention as disclosed by Wudel (Column 9, lines 8-10). Wudel teaches of making powdered mixes with protein comprising stabilizers including carboxymethylcellulose (also known as cellulose gum), wherein the preferred amount of stabilizer ranges from 0.7 to 2% by weight (Column 9, line 10). Thus, powdered compositions comprising protein were known to be made with stabilizers in amounts overlapping the range of the applicant, as taught by Wudel. Stabilizers act as binders or fillers and to produce smoothness in body and texture of the powdered composition upon reconstitution. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cravero and include stabilizer in an amount taught by Wudel. One of ordinary skill would have been motivated to modify Cravero at least for the purpose of providing sufficient amount of stabilizer (i.e., carboxymethylcellulose) to effectively act a binder or filler for the protein composition and to produce smoothness in body and texture of the powdered composition upon reconstitution.

Regarding **claims 9 and 12**, Cravero discloses of powdered composition, that can be reconstituted with water, milk or fruit juices (Column 6, lines 60-61), i.e., Cravero discloses of a method of producing the protein powder in a liquid medium. However, Cravero does not teach "heating the liquid, and homogenizing the liquid". Wudel teaches a powder composition comprising protein (Abstract last 2 lines, Column 9, lines 64-68 and Examples VI to IX, where the dry mix is designated by letter D). Wudel also teaches of adding the dry mix to liquid, such as cream and skim milk (Column 21, lines 59-63) to make suspension in a liquid, further teaching pasteurizing (by heating) and homogenizing the liquid (Column 22, lines 20-25 and Column 11, lines 40-45). Thus, process steps of heating and homogenizing were well known in the art for reconstituting a powdered or dry component, as taught by Wudel. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cravero to include the steps of heating the liquid, and homogenizing the liquid to produce a protein-

containing drink. One of ordinary skill would have been motivated to modify Cravero at least for the purpose of uniformly reconstituting the dry product by homogenizing to eliminate aggregates that may have formed due to interaction between various constituents and heating to pasteurize the product (see Wudel, Column 11, lines 40-45) to produce a microbiologically safe drink product.

C) **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cravero (US 6033691) and Wudel as applied to claims 9 and 12 above, further in view of Huang (US 2003/0157236 A1), hereinafter Huang.

Cravero has been applied under 35 USC 102 (b) for the rejection of claims 1-2, 5 and 7 and under 35 U.S.C. 103(a) for the rejection of claims 3-4.

Note: "pH Values of Various Foods" obtained from CSPAN , Bad Bug Book http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/ucm122561.htm,
is relied upon as an evidentiary reference to show the pH values of fruit juices and milk products.

Regarding the limitation of **claim 10**, wherein the liquid is acidified to a pH value of less than 4.5 after dissolving the powder, it is noted that Cravero discloses a product having pH in the range of 4.45-4.65 (Column 7, lines10-15) and also discloses of powdered composition, that can be reconstituted with water, milk or fruit juices (Column 6, lines 60-61), i.e., Cravero discloses of a method of producing the protein powder in a liquid medium including juices.
Typically fruit and vegetable juices are acidic in nature and milk, especially buttermilk and acidophilus milk can be acidic as well, as evidenced by the list of pH values of food products. According to pH values buttermilk and acidophilus milk and juices of apple, orange, pineapple, grapefruit etc., are acidic. Thus, addition of acidic juices to

reconstitute the powder of Cravero would result in lowering the pH of the reconstituted drink product.

Further, making protein containing foods acidic was known at the time of the invention, for example, Huang teaches of protein containing suspensions or beverages, where the when the protein and stabilizer mixture is hydrated, the pH is adjusted to 3.0 to 5.5 to form an aqueous acidic protein suspension (Publication page 6, Para 0053). Huang also teaches that the hydrating solution may be acidified to a desired pH to below 5.5 by adding an acidulant as an edible acid or by mixing hydrating liquid with acidic liquid, such as fruit or vegetable juice or juice concentrate (Publication page 6, Para 0053). Huang's motivation for reducing the pH of the protein solution is to acidify the hydrated protein solution to other than the isoelectric point (where the protein becomes insoluble or precipitates) of protein material to avoid maximum insolubility of the protein in the acidified solution (Publication page 6, Para 0053, last 3 lines).

Thus, Cravero teaches of an acidic product (having pH in the range of 4.45-4.65 Column 7, lines10-15) and also teaches of reconstituting with juices, which are also typically acidic (as evidenced by pH value of various foods), so the addition of acidic juices to reconstitute the powder of Cravero will result in lowering the pH of the reconstituted drink product. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to make a drink by reconstituting Cravero's product where the resulting drink is acidified to a pH of less than 4.5. One of ordinary skill in the art at the time of the invention would have been motivated to reduce the pH to below 4.5 at least for the purpose of creating a reconstituted drink with a pH other than the isoelectric point of protein material to avoid maximum insolubility of the protein in the acidified solution (Publication page 6, Para 0053, last 3 lines), as taught by Huang.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jyoti Chawla/
Examiner, Art Unit 1781